EUNCL
Nanomedicine Characterisation Laboratory

How can stakeholders access EUNCL?

Nanosafe2016

www.euncl.eu - tna@euncl.eu

Why we need EUNCL?

European Nanomedicine Characterization Laboratory

EUNCL Nanomedicine Characterisation Laboratory

ABOUT US | WORKING WITH US | PARTNERS | DOWNLOADS | PUBLICATIONS | SATELLITES | Search

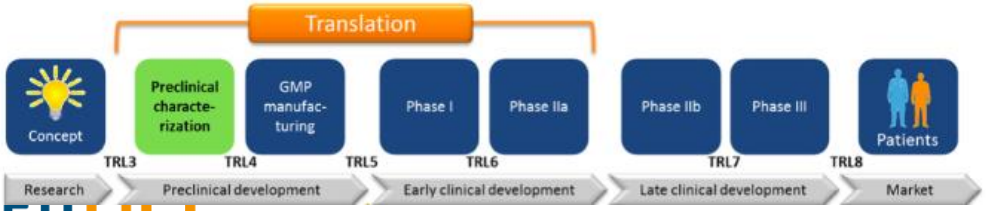
EU-NCL

European Nanomedicine Characterisation Laboratory

Our Mission is:

- To provide a trans-disciplinary testing infrastructure covering a comprehensive set of preclinical characterisation assays (physical, chemical, *in-vitro* and *in-vivo* biological testing) allowing researchers to fully comprehend the biodistribution, metabolism, pharmacokinetics, safety profiles and immunological effects of their Med-NPs.
- To foster the use and deployment of standard operating procedures (SOPs), benchmark materials, and quality management for the preclinical characterisation of Med-NPs (nanoparticles used for medical applications).

To promote inter-sectorial and inter-disciplinary communication among key drivers of innovation, especially between developers and regulatory agencies.



Events where you meet EU-NCL

Biospain 2016 – 5th International Meeting on Biotechnology
28 - 30 September 2016, Bilbao, Spain

ETPN2016
12 - 14 October 2016, Heraklion, Greece

The Fifth International Conference NANOSAFE 2016
7 to 10 November, Grenoble, France

MedTech Forum
30 November to 02 December 2016, Brussels, Belgium

More Events ...

European Nanomedicine Characterisation Laboratory (EU-NCL)

Call for Proposals!

News

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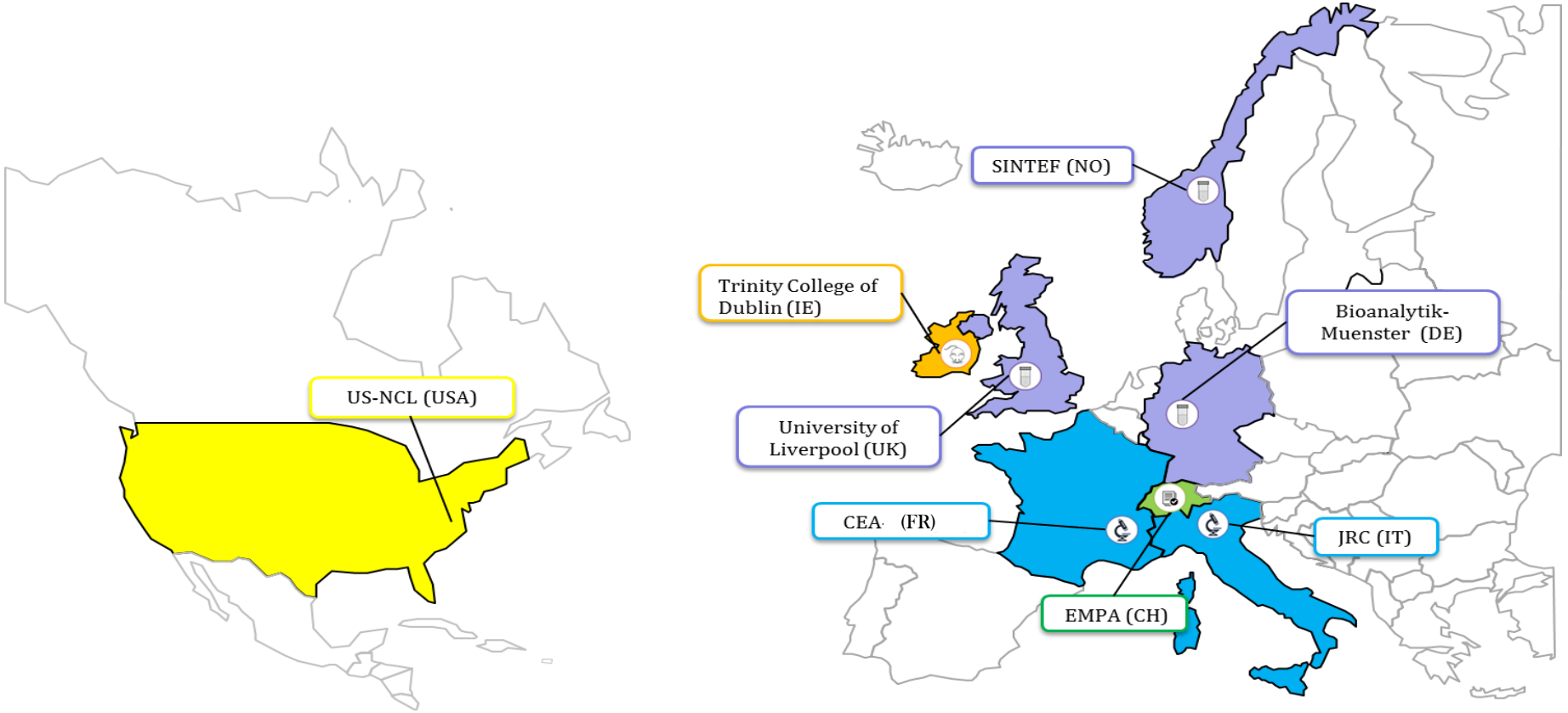
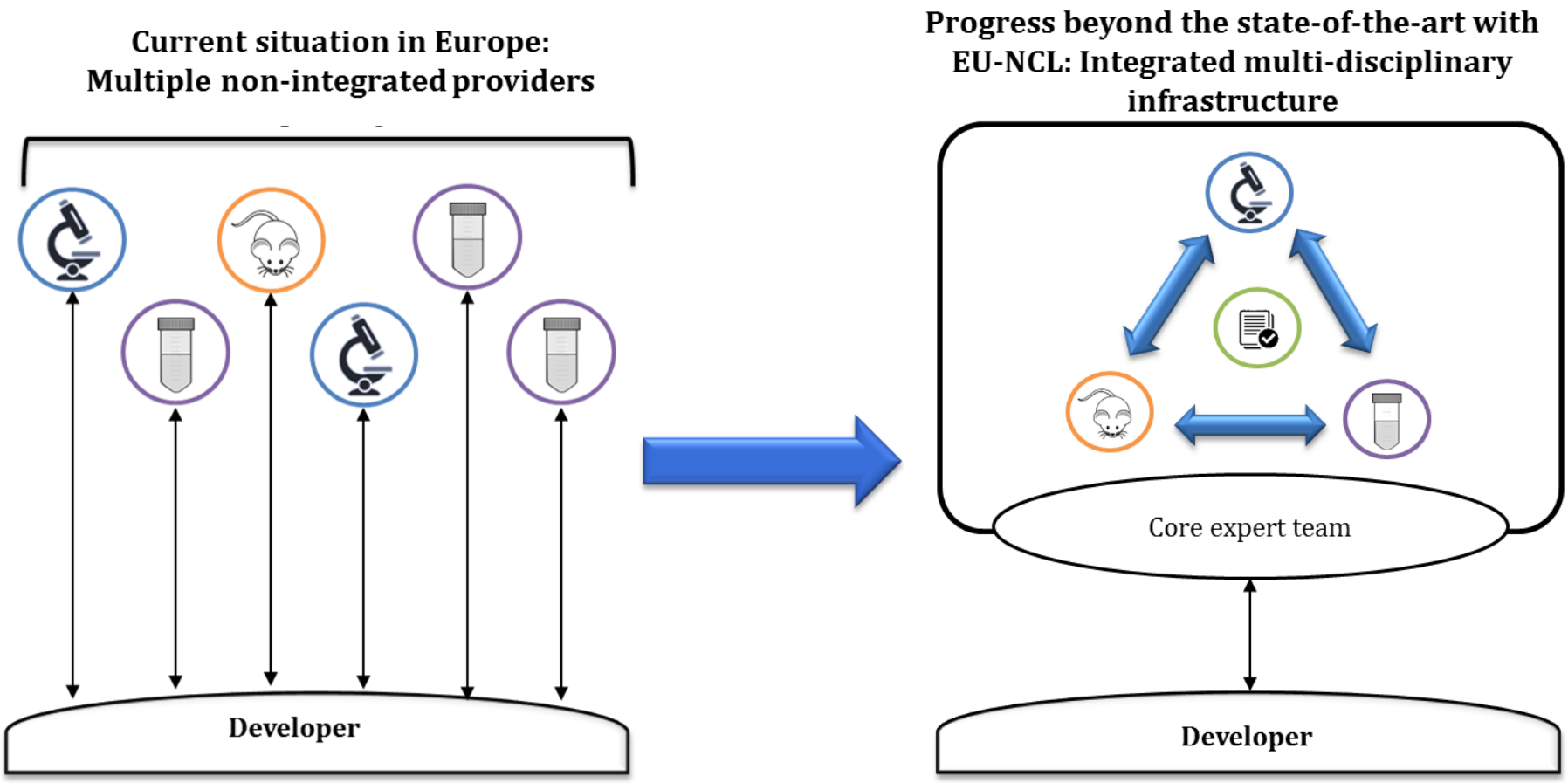
Who we are (core partners)

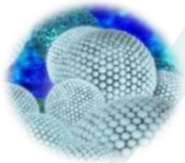


Why we need an EU-NCL?



What EU-NCL offers

European Commission

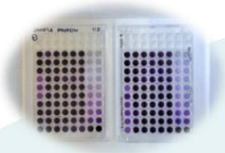


Candidate nanomedicine

PCC

- Size
- Surface potential
- Purity
- Surface morphology
- Composition

....



In vitro

Haematology/ Immunology/ Cytotoxicity

In vivo

-PK Biodistribution

-Immunogenicity Toxicity

-Pharmakokinetic

Final report

The assay cascade is not static – actively adapting/ improving/reviewing!

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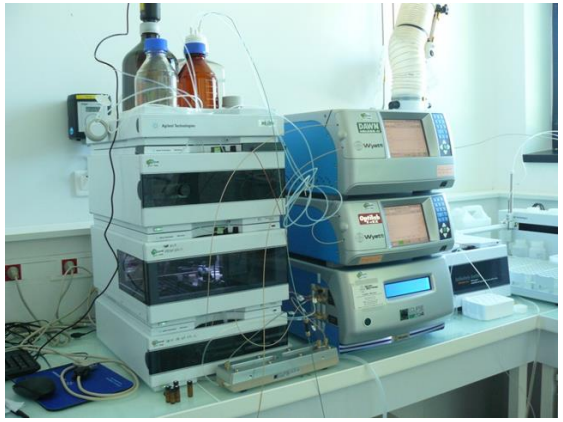
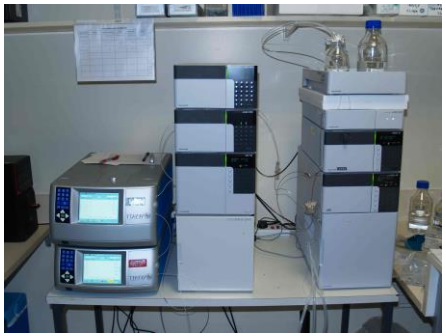
What CEA offers





Physical chemical characterization of Medical Nanoparticles (Med-NPs): e.g. composition, size distribution and morphology:

- **AF4-MALS,**
- **ICP-MS, AF4-ICP-MS,**
- **TEM/Cryo-TEM,**
- **SEC-MALS,**
- **DLS/Zeta Potential,**

Special thanks to:

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Amandine Arnould
François Saint-Antonin
Sylvie Montellier
Isabelle Worms
Mathieu Varache

Standardized and validated SOPs

Step1
- Transfer of the SOPs and of the quality controls from NCI-NCL. Creation of new SOPs
- Qualification: inter-laboratory comparison

Step2
- "Bugged" samples to test our problem solving capability

Step 3
- Validation of all the EUNCL laboratories (inter-laboratory comparison with NCI-NCL)

The Standard Operating Procedures (SOPs) have been qualified and validated in all the laboratories of the EU-NCL consortium..

Quality controls are defined according to the ISO 17025

Who can Apply?

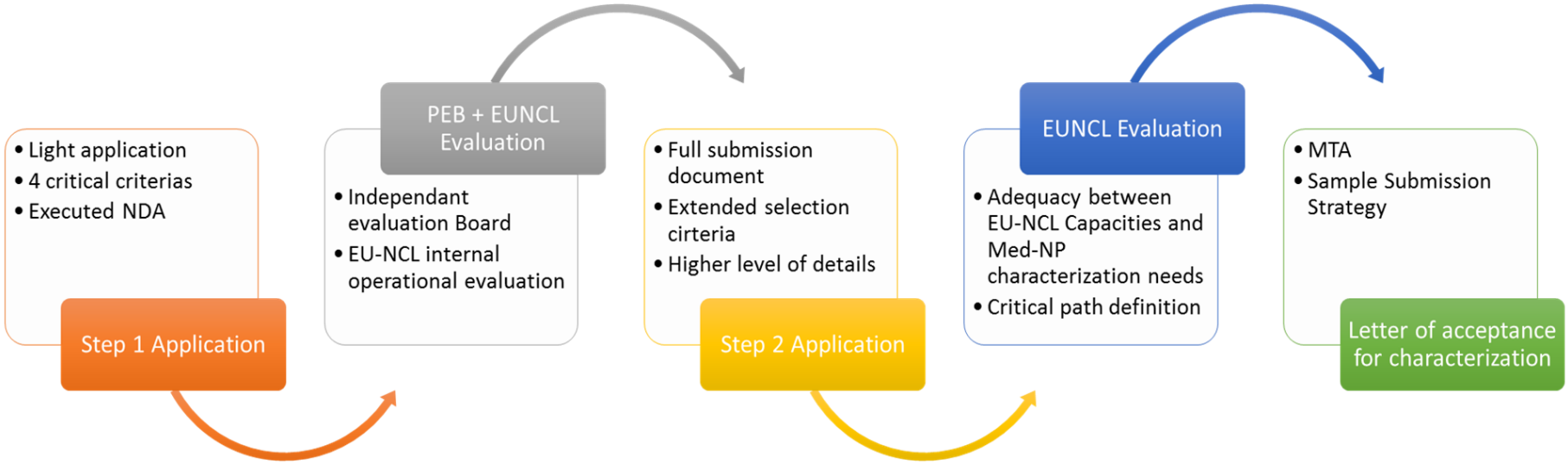
Open to any European developer of medical nanoparticles (Med-NPs)– Industry, SME, Academia, Regulatory Agencies…..

Acceptance criteria:

- Cancer treatment (we will open to other treatments in future campaigns, stay tuned!)
- Proven efficacy of the Med-NP in biological systems
- Ability to produce two independent batches (reproducibility)
- Detailed production plan and its scaling up plan
- Clear strategy to transfer the technology to the clinical environment

Next Deadline: April 2017

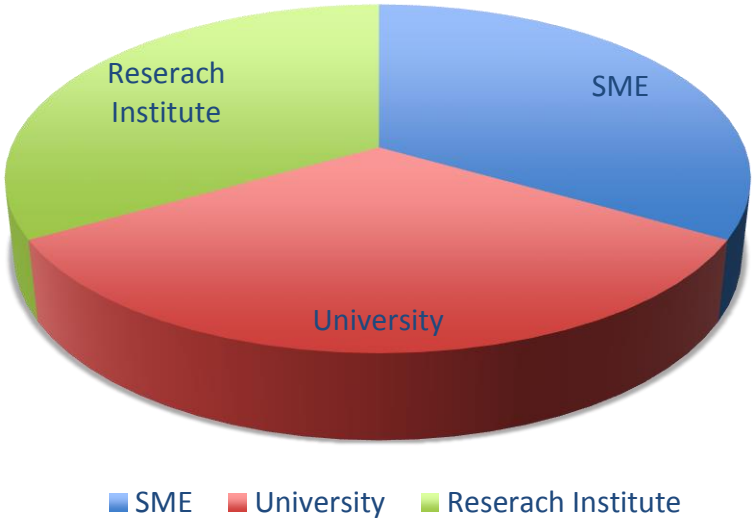
Application process



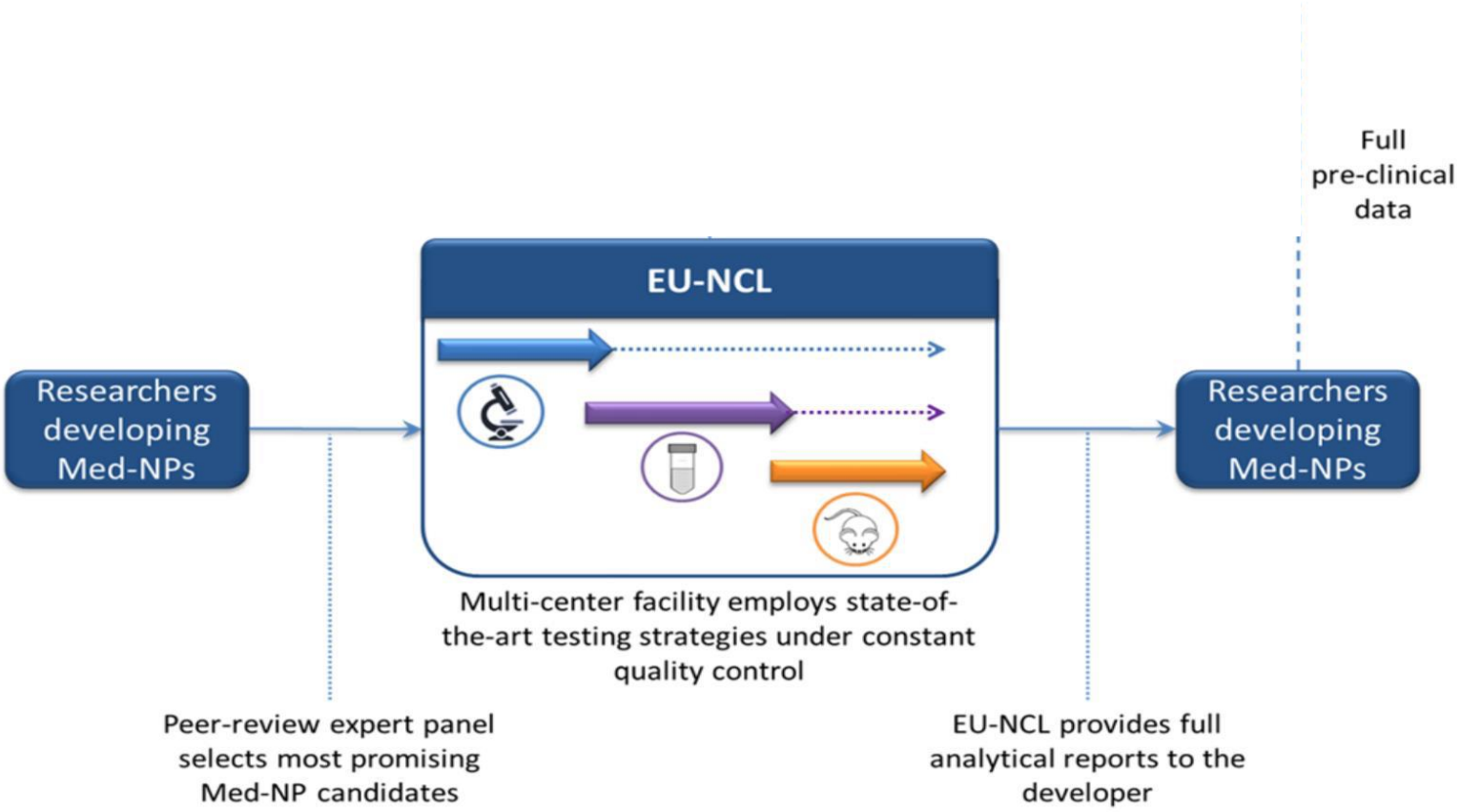
Next Deadline: April 2017

Application profiles

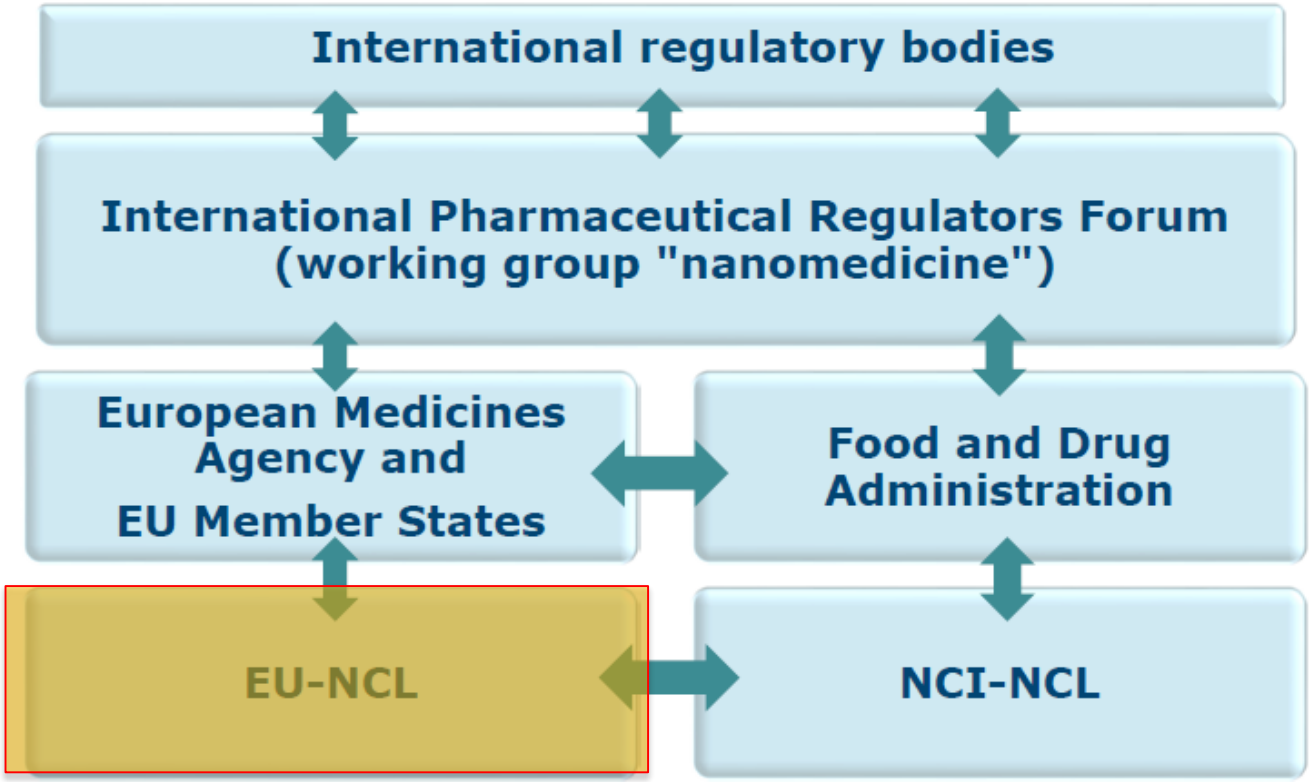
- First Trans National Access (TNA) campaign launched early 2016
- 9 applications in total
  - 6 eligible
  - 5 progressed to step 2
- Types of materials submitted;
  - Organic (liposomes, dendrimers…)
  - Inorganic (GNP, Iron carbide…)
  - Various drugs loaded
- What makes a successful application?
  - DATA AND DATA QUALITY



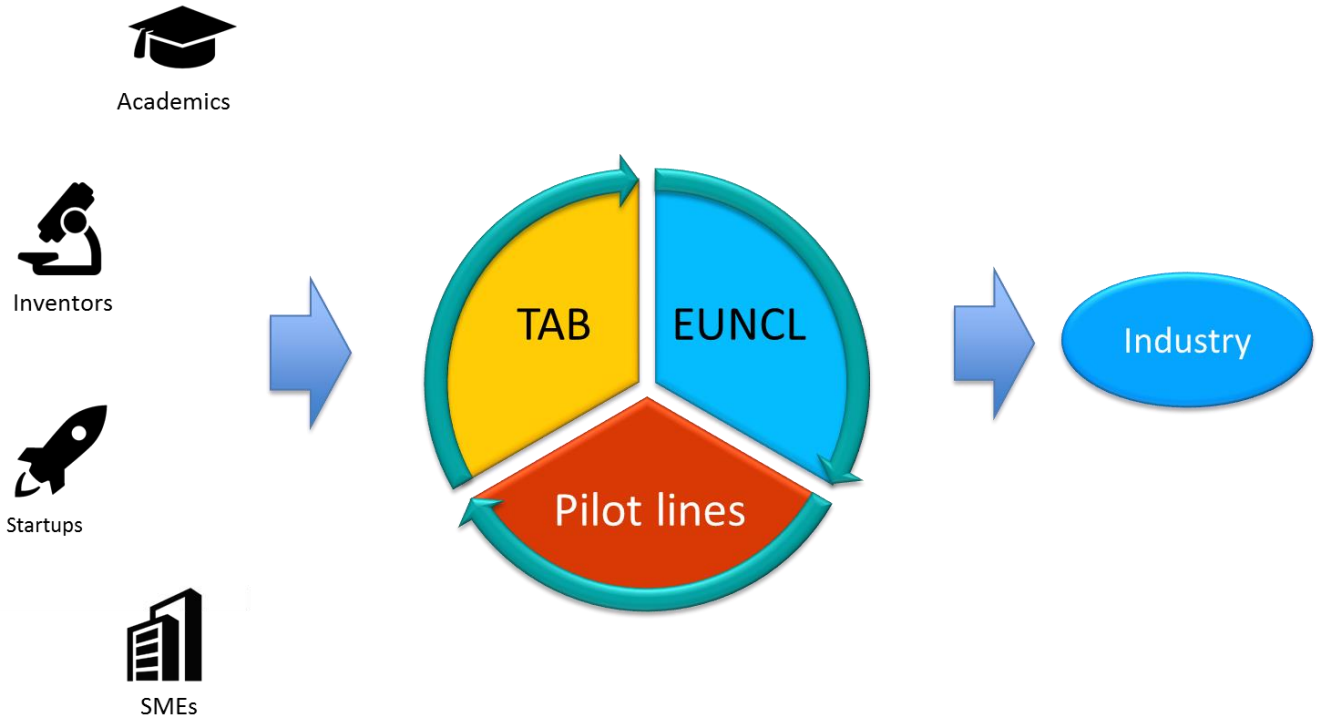
EU-NCL & Regulators: a strategic choice



EU-NCL in the regulatory environment



EU-NCL &
The Nanomedicine Translation Hub



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Thank you

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